

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20571/S9

CHEMISTRY REVIEW(S)

DIVISION OF ONCOLOGY DRUG PRODUCTS
Chemistry, Manufacturing, and Controls

NDA #: 20-571

CHEMISTRY REVIEW

REVIEW DATE: March 23, 2000

SUBMISSION TYPE

Efficacy Supplement-009
Amendment
Amendment

DOC. DATE

October 19, 1999
October 29, 1999
March 21, 2000

CDER DATE

October 19, 1999
November 1, 1999
March 21, 2000

ASSIGNED DATE

February 9, 2000
March 22, 2000

NAME & ADDRESS OF APPLICANT:

Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

DRUG PRODUCT NAME:

Proprietary:

Nonproprietary/USAN: -

Camptosar Injection
Irinotecan Hydrochloride

DOSAGE FORM:

STRENGTHS:

ROUTE OF ADMINISTRATION:

DISPENSED:

Parenteral Solution

20mg/ml

Parenteral use

☒ Rx ☐ OTC

REMARKS/COMMENTS:

CONCLUSIONS & RECOMMENDATIONS:

Considering the following, a request for a categorical exclusion for environmental assessment concerning the efficacy supplement-009 is granted.

- Based on the estimated production of 180kg at the 5th year, the expected introduction concentration was calculated to be 4.0×10^{-3} ppb.
- No extraordinary circumstances exist
- Sixty percent of product is from the cultivated plants. Forty percent of production from the wild plants will be decreased due to initiation of plantation in India and increased future harvesting in Taiwan.
- Only renewable branches are used for the production of camptothecin starting material.
- Preservation practice for the wild plants (e.g. cut one branch per year).
- No increase use of the wild plants is expected due to the approval of this efficacy supplement.

/S/

Sung K. Kim, Ph.D.,
Review Chemist, HFD-150

cc:

Orig. NDA 20-571

HFD-150/Division File

HFD-150/BAtkins

HFD-150/SKim

HFD-150/RWood

R/D Init. by: gah for RHW 3-23-00